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Attorneys for Defendants
C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability
Litigation,

No. 2:15-MD-02641-DGC

**DEFENDANTS' SEPARATE
STATEMENT OF FACTS IN
SUPPORT OF MOTION FOR
SUMMARY JUDGMENT AS TO
PLAINTIFF DEBRA MULKEY'S
CLAIMS**

DEBRA MULKEY, an individual,

(Assigned to the Honorable David G.
Campbell)

Plaintiff,

v.

C. R. BARD, INC., a New Jersey
corporation and BARD PERIPHERAL
VASCULAR, INC., an Arizona
corporation,

Defendants.

Pursuant to Fed. R. Civ. P. 56(c), Local Rule 56.1(a), and Case Management Order No. 53 (Doc. 5770), Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively “Bard”) respectfully submit this Separate Statement of Facts in Support of Motion for Summary Judgment as to Plaintiff Debra Mulkey’s Claims.

1. Plaintiff Debra Mulkey received a Bard Eclipse® Filter (the “Filter”) on April 11, 2012, before she underwent bariatric surgery. (Ex. A, Plaintiff Fact Sheet of Plaintiff Debra Mulkey (hereinafter “PFS”), at §§ II.2(a), II.3.)

2. The Filter is not sold directly to patients. (Ex. B, Eclipse Filter Instructions for Use (the “Eclipse IFU”) at page 1.)

3. Plaintiff’s implanting physician, Dr. Roderick Tompkins, testified that he placed the Filter in Plaintiff [REDACTED] (Ex. C, April 11, 2017 Dr. Roderick Tompkins Deposition Transcript (“Tompkins Dep. Tr.”) at 176:2 to 177:10.)

4. At the time Plaintiff received her Filter, [REDACTED]
[REDACTED]
[REDACTED] (Ex. D, Selected Plaintiff Medical Records.)

5. Dr. Tompkins testified that before he placed the Filter, he had the IFU that accompanied the Filter available to him to read. (Ex. C, Tompkins Dep. Tr. at 173:6-24.)

6. The Eclipse IFU applicable in April 2010 (when Plaintiff received her Filter) included the following warnings:

a. Under the bolded heading “**Potential Complications**,” the Eclipse IFU reads as follows:

- Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. . .
- Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications

with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.

- Perforation or other acute or chronic damage of the IVC wall.

* * *

- Filter Tilt

* * *

All of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ration for a patient who is at risk of pulmonary embolism without intervention.

(Ex. B, Eclipse IFU.)

b. Under the bolded “**Eclipse Filter Removal**” heading, the Eclipse IFU states in bolded language as follows:

It is possible that complications such as those described in the “Warnings”, “Precautions,” or “Potential Complications” sections of this Instructions for Use may affect the recoverability of the device and result in the clinician’s decision to have the device remain permanently implanted.

(Ex. B, Eclipse IFU.)

7. Dr. Tompkins testified that he would be speculating as to whether information and alleged facts told to him by Plaintiff’s counsel would have altered his treatment decision for Plaintiff. Specifically, he testified as follows:

13 Q And it’s important for you to rely on
14 accurate or reliable information, isn’t that
15 right --
16 A Yes.
17 Q -- in making a decision as a medical

18 doctor?

19 A Yes.

20 Q Okay. So -- so again, being shown a
21 draft e-mail and asked if you had known, if you
22 had known, would you have made a different
23 decision, *you're really speculating, aren't you?*

24 MR. DeGREEFF: Object to the form.

25 A *Yes*.

1 Q Doctor, would you need much more
2 information other than an e-mail or a couple of
3 documents provided to you with testimony by
4 counsel in making a decision whether you would use
5 a product or not?

* * *

8 A Can you restate that?

9 Q Sure.

10 Would you need information beyond
11 documents taken out of context -- internal
12 documents taken out of context to make a decision
13 as to whether you would use a product or not?

14 MR. DeGREEFF: Object to form. Same
15 objection.

16 A Yes.

(Ex. C, Tompkins Dep. Tr. 184:13 to 185:16.)

8. Dr. Tompkins never testified that had he been given different information about the Eclipse Filter, it is probable that he would have decided against using the device.

9. Dr. Tompkins testified that he relied on his experience, the experience of his colleagues, and the applicable medical literature when he decided to implant an Eclipse Filter in Ms. Mulkey. (Ex. C, Tompkins Dep. Tr. 202:7-22.)

10. Dr. Tompkins testified that he does not rely on information from medical device manufacturers, such as Bard, when deciding which IVC filter he wanted to use. Specifically, Dr. Tompkins testified as follows:

19 Q So -- so in -- in deciding which --
20 which filter to use, do you rely on information
21 from the manufacturer?

22 A No.

(Ex. C, Tompkins Dep. Tr. 88:19-22.)

11. Dr. Tompkins testified he does not recall discussions with Bard's sales representatives regarding the use of IVC filters in bariatric patients. (Ex. C, Tompkins

1 Dep. Tr. 55:10-13.)

2 12. Dr. Tompkins testified that he discussed with Ms. Mulkey the risks and
3 benefits of IVC filter placement, and then obtained her informed consent before placing
4 the Filter. (Ex. C, Tompkins Dep. Tr. at 80:22 to 81:5; 86:3-11; 94:2-15.)

5 13. On May 21, 2012, Plaintiff [REDACTED]
6 [REDACTED] (Ex. D, Selected Plaintiff Medical Records.)

7 14. On October 4, 2012, Ms. Mulkey underwent an unsuccessful percutaneous
8 Filter removal procedure with Dr. Pho Nguyen. (Ex. D, Selected Plaintiff Medical
9 Records.)

10 15. The operative note from Plaintiff's October 4, 2012, [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED] (Ex. D, Selected Plaintiff Medical Records.)

14 16. Plaintiff testified that on October 4, 2012, she understood Dr. Nguyen "was
15 having some problems" trying to remove the Filter, that the Filter "had grown into the
16 vein," that further attempts to remove the Filter could "caus[e] too much damage to my
17 vein," and that, as a result, Dr. Nguyen would be unable to retrieve her Filter. (Ex. E,
18 February 8, 2017 Debra Mulkey Deposition Transcript ("Mulkey Dep. Tr.") at 95:17 to
19 97:1.)

20 17. Plaintiff testified that on October 4, 2012, she understood there was "some
21 reason" why Dr. Nguyen was unable to remove her Filter. (Ex. E, Mulkey Dep. Tr. at
22 99:7-10.)

23 18. Plaintiff testified that on October 4, 2012, she knew she no longer needed
24 her Filter. (Ex. E, Mulkey Dep. Tr. at 97:13-17.)

25 19. Plaintiff testified that on October 4, 2012, she was "upset" that her filter
26 could not be removed. (Ex. E, Mulkey Dep. Tr. at 185:3-9 ("[I]t upset me when I found
27 out it [the Filter] couldn't be removed."))

28 20. Plaintiff testified that the first time she experienced symptoms of any bodily

1 injuries related to her Filter was on October 4, 2012, the day of her unsuccessful removal
2 procedure. (Ex. E, Mulkey Dep. Tr. at 142:8-24.)

3 21. Plaintiff claims that “[i]n October 2015, I saw a commercial on TV that
4 indicated that IVC filters were causing bodily injuries to people.” (Ex. A, PFS at
5 § II.13(c).)

6 22. Plaintiff testified that she never talked to any of her doctors about her IVC
7 filter until December 2016. (Ex. E, Mulkey Dep. Tr. at 103:12 to 104:6.)

8 23. Plaintiff’s vascular and interventional radiologist expert, Dr. Darren Hurst,
9 testified that Ms. Mulkey’s Filter could be removed via a complex percutaneous
10 procedure. (Ex. F, July 21, 2017 Dr. Darren Hurst Deposition Transcript (“Hurst Dep.
11 Tr.”) at 100:20 to 101:14.)

12 24. Plaintiff’s cardiothoracic surgeon expert, Dr. Derek Muehrcke, testified that
13 Ms. Mulkey’s Filter could “likely” be removed via a complex percutaneous procedure.
14 (Ex. G, July 24, 2017 Dr. Derek Muehrcke Deposition Transcript (“Muehrcke Dep. Tr.”),
15 at 154:22 to 155:14.)

16 25. Plaintiff’s expert, Dr. Muehrcke, acknowledges that all IVC filters are
17 known to have potential complications, including filter fracture, migration, tilt, and
18 perforation. (Ex. G, Muehrcke Dep. Tr. at 55:22 to 57:9.)

19 26. Dr. Hurst testified that Ms. Mulkey’s filter perforated her IVC, caudally
20 migrated, and fractured. (Ex. F, Hurst Dep. Tr., at 74:23 to 75:16.)

21 27. Plaintiff testified that she never received a patient card or brochure
22 regarding her IVC filter. (Ex. E, Mulkey Dep. Tr. at 67:11-18.)

23 28. Plaintiff testified that she never asked for any information about her filter
24 before it was implanted. (Ex. E, Mulkey Dep. Tr. at 67:16-18.)

25 29. Plaintiff testified that she has never spoken to anyone at Bard. (Ex. E,
26 Mulkey Dep. Tr. at 167:11-13.)

27 30. Plaintiff testified that she has never visited Bard’s website. (Ex. E, Mulkey
28 Dep. Tr. at 69:24 to 70:1.)

31. Plaintiff testified that she did not know that Bard was the manufacturer of her IVC filter until after she contacted her lawyer about her potential legal claim. (Ex. E, Mulkey Dep. Tr. at 66:23 to 67:1.)

RESPECTFULLY SUBMITTED this 28th day of August, 2017.

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**Attorneys for Defendants C. R. Bard, Inc. and
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CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of August 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/Richard B. North, Jr.
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